

REMARKS

Claims 26-36 are pending following entry of this Amendment. Claim 28 is the only pending independent claim. Claim 25 has been canceled without prejudice, as being redundant in view of the amendment to claim 28. Although claims 26, 27, 29, 33 and 34 have been withdrawn by the Examiner, reconsideration, examination and allowance of claims 26, 27, 29, 33 and 34 are sought for the reasons noted below. Claims 35 and 36 have been added.

Initially, the Applicants would like to thank Examiners Ford and Minnifield for the courteous telephone interview of April 15, 2003, with the undersigned attorney, during which portions of the Office Action were clarified, particularly with reference to the rejections under 37 U.S.C. §112, first paragraph, as well as discussions relating to U.S. Patent 6,197,312 of Peak *et al.* (hereinafter "Peak"). The telephone interview will be summarized hereinafter.

Support for Amended and New Claims in the Specification

Claim 28 has been amended, without prejudice, to incorporate the recitations of claim 25 in subparagraphs (i) – (v) regarding the conserved region of SEQ ID NO:11, and to incorporate recitations (a) – (d) regarding the variable region of SEQ ID NO:11. Both of these aspects of the amendment are supported by the designations of conserved (C) regions and variable (V) regions of SEQ ID NO: 11 in Table 1 at page 55 of the application as filed. The recitation in claim 28 that the protein has at least one fewer variable region than a wild-type NhhA polypeptide is well supported in the application as filed, for example at page 11, line 11, to page 12, line 4. Moreover, the proteins described in the Examples beginning at page 41 of the application have the characteristics claimed in claim 28.

New claims 35 and 36 are fully supported by the application as filed, for example, at page 15, lines 11-13. Moreover, claims 35 and 36 are not redundant with respect to claim 30, since claim 30 is directed to allelic variant, whereas claims 35 and 36 are not necessarily directed to an allelic variant.

For the foregoing reasons, the additions and amendments made herein do not include new matter.

Drawings

New drawing Figs. 1A through 1E, 2A through 2H and 10A and 10B are enclosed herewith. As indicated in the amendment portion above, new figure legends have been added to correct the figure legends of the corresponding presently pending drawing figures, which the official Draftsperson said contained black ink and were poor in quality. No substantive changes were made to the drawings, so no new matter has been added.

Election of Species

The Examiner considers claims 26, 27, 29, 33 and 34 to be withdrawn from consideration. In the Examiner's view, these claims are directed to non-elected species. In paragraph 1 at page 2 of the Office Action, the Examiner asserted that the Applicants "elected without traverse of Group II, claims 10-16, SEQ ID NO:11, residues 109, 120," in their response filed April 22, 2002, and concluded that because of this, claims 26, 27 and 29 were not examined because they are directed to non-elected species, even though a requirement to elect specific residues was withdrawn in a previous Office Action. No reasoning was set forth in the Final Rejection (the first Office Action following the addition of claims 33 and 34) for determining that claims 33 and 34 are directed to a non-elected species.

The Applicants respectfully point out to the Examiner that her quoted assertion is not fully accurate. In the Amendment filed April 22, 2002, it was only Group II, claims 10-16, which were elected without traverse, but Applicants provisionally elected, with traverse to prosecute SEQ ID NO:11, residues 109-120. As noted in the Final Rejection, the requirement to elect specific residues (*i.e.*, residues 109-120) had already been withdrawn in a previous Office Action. Accordingly, the basis for the Examiner's determination that claims 26, 27 and 29 are directed to a non-elected species, appears not to be well-founded. The Applicants again respectfully remind the Examiner that SEQ ID NO: 11 is a consensus sequence that, by its definition (*e.g.*, see the sequence listing) incorporates each of SEQ ID NOs: 1-10. Claim 26, directed to a protein of claim 28 comprising at least 12 contiguous amino acids of a sequence from SEQ ID NOs:1-10 is clearly contemplated as being within a consensus SEQ ID NO:11. See Table 1 at page 55 and the sequence listing, where at least 12 contiguous amino acids are fully set forth. Similarly, the residue alignment of SEQ ID NO:11 in Table 1 supports the

residue alignment claimed in claim 27. Moreover, claim 27 corresponds to original elected claim 11.

Claim 29 corresponds to original elected claim 13. As explained in the application at page 3, last paragraph, the sequences claimed in claim 29 are directed to certain modified polypeptides of the invention and are believed to be within the scope of the elected species. The Applicants respectfully submit that claims 26, 27, and 29 should not be considered withdrawn, and request that the Examiner consider the merits of these three claims together with the other pending claims.

Claims 33 and 34 are even more clearly within the scope of the elected species and fall squarely within the scope of amended claim 28. The Examiner's attention is directed to Example 4, at page 44, where SEQ ID NO:23 comprises C1, C4 and C5, as well as V3 and V4, while also including portions of V1 and C3. V2 and C2 are deleted in this sequence. Therefore, the isolated protein comprises at least one conserved (C) region (in this case, the full C1, C4 and C5 regions), and at least one V region (in this case, the full V3 and V4 regions). Moreover, since the V2 region has been deleted, it contains one fewer V regions than a wild-type NhhA polypeptide.

With respect to SEQ ID NO:35, claimed in claim 34, the C1 region (the N-terminal leader) has been deleted with respect to SEQ ID NO:23 that was claimed in claim 33. Thus, it should be clear that claims 33 and 34 were and continue to be within the elected species.

Reconsideration and withdrawal of the restriction and election requirements and examination of all of the pending claims 26-36 are respectfully solicited.

Claim Rejections Pursuant to 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 28 and 30-32 were rejected pursuant to 35 U.S.C. § 112, first paragraph, in item 5 of the Office Action, based on an asserted lack of a suitable written description and lack of enablement. Claim 25 has been canceled, and its recitations have been incorporated into claim 28. Both in the Office Action and during the telephone interview, the Examiner referred to the language of then-pending independent claim 28 which used the open-ended term "comprising", and then referred to the written description and the various descriptions within the specification relating to "variants" or "fragments." As understood, the Examiner's position is that the unrestricted open-ended language of claim 28, prior to the present Amendment, and the broad

scope of the invention described in the specification, made the claim so broad that it was not adequately described in the specification and the full breadth of the claim was not enabled. The Applicants respectfully disagree with the Examiner's conclusions for the reasons set forth in the response to the last Office Action. However, to advance the prosecution of this application, claim 28 has been amended for purposes of clarification. Thus, claim 28 now indicates that the isolated protein still comprises at least one conserved region of SEQ ID NO:11, but recites that the conserved region consists of five recited amino acid residue groups. Claim 28 also provides that the isolated protein has at least one variable region, and that the variable region or regions consist of an amino acid sequence selected from four specific amino acid groups. As noted above, the subject matter of claim 28 is derived from Table 1 at page 55 of the application and clearly has an adequate written description at least there and in the Examples, beginning at page 41 of the specification. The Examples, together with Table 1, the exemplary substitutions set forth in Table 2, and the sequence listings, not only provide a written description that clearly evidences the Applicants' possession of the invention, but also evidences the enablement of the full scope of independent claim 28, as well as the other pending claims which depend directly or indirectly from claim 28.

It should be noted that claim 28 still encompasses a variety of possible amino acid substitutions at residues marked "X" in SEQ ID NO:11. However, the sequence listing specifies that each non-conserved residue can be any of the residues present in the corresponding molecule of SEQ ID NOs:1-10, since SEQ ID NO:11 is a consensus sequence listing. Moreover, any absent amino acid in SEQ ID NO:11 is also absent at that particular position in any one of SEQ ID NOs:1-10. Thus, the substitutions of the non-conserved regions are not limitless or unspecified. The Applicants clearly were in possession of the invention as of the filing date, in that they specified the substitutions that could be made. Furthermore, in view of the present disclosure, an ordinarily skilled artisan reviewing the present application would be able, without undue experimentation, to make any protein that is within the scope of claim 28 or the other pending claims.

The Applicants respectfully contend that the specification provides an adequate written description of the information that is necessary for a skilled artisan to envision and design the structure of any of the isolated proteins recited in the claims, as well as how to make and use them, and that both the written description requirement and the enablement requirement are

therefore satisfied. Reconsideration and withdrawal of the Examiner's rejection of claims 25, 28, and 30-32 pursuant to 35 U.S.C. § 112, first paragraph, are respectfully requested for this reason alone.

Claim Rejections Pursuant to 35 U.S.C. § 102(e) over Peak

Claims 25, 28, and 30-32 were rejected pursuant to 35 U.S.C. § 102(e) over Peak (U.S. Patent no. 6,197,312). Peak was discussed during the telephone interview. Peak is directed to polypeptides obtained from wild-type *N. meningitides*, and nucleotide sequences encoding such polypeptides, as well as their use. The first issue is whether Peak is an appropriate prior art reference under 35 U.S.C. §102(e) against the present application. It is noted that two of the three inventors of Peak (Messrs. Peak and Jennings) are co-inventors in the present application. Nevertheless, assuming only for the sake of argument that Peak is an appropriate prior art reference under 35 U.S.C. §102(e), Peak neither anticipates nor renders obvious the invention of the present application as set forth in claim 28 and in the claims depending from claim 28. Although the *N. meningitides* is a common starting material in Peak and in the present invention, Peak does not identify the particular conserved and variable regions of SEQ ID NO:11 as now claimed in the present application. This is particularly the case with the variable regions, as the boundaries of the presently identified variable regions cannot be reasonably considered to have been disclosed in Peak.

Furthermore, although in the Office Action, the Examiner referred to a general disclosure in Peak relating to deletion mutants, there is no explicit disclosure of a mutant having at least one fewer variable region as defined in claim 28, compared to a wild-type NhhA polypeptide as disclosed in Peak. The Applicants respectfully submit that to derive the presently claimed invention from Peak would be to rely on hindsight based on the invention disclosed in the present application, which is not appropriate. Thus, Peak does not disclose and would not suggest to a person of ordinary skill in the art at the time of the present invention the subject matter now claimed in this application.

Conclusion

In view of the arguments and amendments presented herein, the Applicants believe that each of claims 26-36 is in condition for allowance. Reconsideration and allowance of these claims are respectfully requested at the earliest possible time.

Respectfully submitted,

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